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Revision of the EU's Infant Formulae and Follow-on Formulae Directive

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Report Highlights:
The European Commission has launched an open consultation on the revision of Commission Directive 91/321/EEC on infant-formulae and follow-on formulae.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Brussels USEU [BE2]
[E3]

Revision of the Infant Formulae and Follow-on Formulae Directive

Intro

The European Commission has launched an open consultation on the revision of Commission Directive 91/321/EEC on infant-formulae and follow-on formulae. European organizations having an interest in this legislative initiative are invited to comment on the proposed amendment to the directive. Organizations can submit comments until March 31, 2005.

The Commission's working document on the proposed changes, an introductory paper and a letter sent by the Commission to representative European organizations can be downloaded from the Internet at http://europa.eu.int/comm/food/consultations/index_en.htm.

Proposed Changes

The main changes that are being proposed to Commission Directive 91/321/EEC are:

- **Definitions of "infant formulae" and "follow-on formulae"**: the definition has been revised to ensure that there is consistency between the definitions of both infant formulae and follow-on formulae.

- **Inclusion of new ingredients** - four possible approaches to the inclusion of new ingredients have been outlined:
1) The existing system – on request manufacturers make available the scientific dossier substantiating the suitability and safety of the new ingredient.
2) A notification system – the manufacturer notifies the competent authorities when an infant formulae containing a new ingredient is placed on the market.
3) A temporary authorization – the Commission obtains delegated power to authorize the use of a new ingredient following evaluation by the European Food Safety Authority (EFSA) but prior to amendment of the specific directive through the legislative procedure.
4) Approval of a new ingredient through the Regulatory Committee procedure following evaluation by EFSA.

- **Labeling and claims**: labeling provisions will need to be updated to reflect the proposed changes in the definition and composition of infant formulae and follow-on formulae. The list of permitted claims will be reviewed and extended.

- **Essential composition** of infant formulae and follow-on formulae: a number of changes to the essential composition are being proposed.

- **Reference values for nutrition labeling**: new labeling reference values for certain vitamins and mineral elements are being proposed taking into account the national recommended daily intakes.

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Report Number	Title	Date Released
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